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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,477	08/04/2003	Paul Lehmann	21368	8405

EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

151 7590 12/12/2007  
HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/634,477	<b>Applicant(s)</b> LEHMANN ET AL.	
	<b>Examiner</b> Hope A. Robinson	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-16,19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1,5-15,19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.
2. Applicant's response to the Office Action mailed March 13, 2006 on June 15, 2006 is acknowledged.

### ***New-Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 6 is confusing as the claims lists items (d-g), however there is no nexus between these and the recited analog. Clarification is required as set forth in for example items (a-c).

***Basis For NonStatutory Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 5-15 and 19, 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-14 of copending Application No. 10/706,701. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either

anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from heart disease comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta; SEQ ID NO:1; a modification of 1 to 6 glycosylation sites; a darbepoetin; pegylated; and a conjugate having a particular structure. The instant application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from diabetes (type II) comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta; SEQ ID NO:1; a modification of 1 to 6 glycosylation sites; a darbepoetin; pegylated; and a conjugate having a particular structure. The copending application claims differ from the instant application in that the patient is suffering from heart disease, whereas the instant application patient is suffering from diabetes, however, the methods have one step, administering erythropoietin, thus the resulting effect will be the same. Moreover, the art generally recognizes that heart disease is a risk with diabetes, for example type II diabetes. In fact, studies have shown that there is a five-fold increase in the risk for heart disease in women with diabetes, thus the administration of erythropoietin is critical to both diseases claimed in the applications. Note that the Silverberg et al. reference of record is treating a patient having anemia, congestive heart failure and type II diabetes with EPO. Therefore, the two sets of claims

differ in scope but are obvious one over the other, as the intended use does not materially change the composition administered.

6. Claims 1, 5-12 and 19, 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4-15 of copending Application No. 11/013,560. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from chronic inflammatory intestinal disease comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta; SEQ ID NO:1; a modification of 1 to 6 glycosylation sites; a darbepoetin; pegylated; and a conjugate having a particular structure. The instant application claim 1 is directed to a method of treating disturbances in iron distribution in a patient suffering from diabetes (type II) comprising administering a therapeutically effective amount of human erythropoietin. The dependent claims hereto are directed to an erythropoietin that is epoetin alfa or beta; SEQ ID NO:1; a modification of 1 to 6 glycosylation sites; a darbepoetin; pegylated; and a conjugate having a particular structure. The

instant application claims differ from the copending application in that the patient is suffering from diabetes, whereas the copending application patient is suffering from chronic inflammatory intestinal disease, however, the methods have one step, administering erythropoietin, thus the resulting effect will be the same. Thus, the two sets of claims differ in scope but are obvious one over the other, as the intended use does not materially change the composition administered.

#### ***Response to Arguments***

7. The response filed has been considered.. Note the rejections under 35 U.S.C. 112, first and second paragraphs, 102 and 103 are withdrawn based on amendments to the claims and/or applicant's arguments. The double patenting rejections remain and a new rejection made under under 35 U.S.C. 112, second paragraph. Applicant's comments regarding withdrawn rejections will not be addressed since moot since the rejections no longer exist. However, the comments made regarding the double patenting will be addressed. Applicants state that the ODP rejections are premature and that claims have been amended and the instant claims do not require the absence of iron. This argument is not persuasive as the instant claims are like a genus claim, furthermore, the instant claim 6 requires the absence of iron. Thus, the rejections remain since no TD was filed.

#### ***Conclusion***

8. No claims are allowable.

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Art Unit: 1652


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957.

The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Primary Examiner

HOPE ROBINSON  
PRIMARY EXAMINER